Bayer CropScience

476511-00

Ms. Sheryl Reilly
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard,
2777 S. Crystal Dr.,
Alexandria, VA 22202

Attn: Denise Greenway

December 22, 2008

Subject: Registration application for BCS Cry1Ab cotton event T304-40 cotton. Active ingredient *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (pTDL008)
EPA CODE B800

Dear Ms. Greenway:

Bayer CropScience (BCS) respectfully submits this registration application for the active ingredient *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production in event T304-40 cotton plants under section 3 of the Federal Insecticide, Fungicide and Rodenticide Act. The *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production in event T304-40 cotton plants is covered by the existing tolerance exemption issued under 40 CFR 180.1173 for the *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production in all plants.

With this letter and enclosed materials, BCS is applying for a registration of Cry1Ab cotton event T304-40. BCS does not intend to offer this individual product for sale. BCS intends to produce commercially a cotton line called TwinLink™ cotton, obtained by conventional breeding of the Cry1Ab cotton event T304-40 and the Cry2Ae cotton event GHB119. A registration application for the Cry2Ae cotton and the combined event are being submitted concurrently in a separate application.

Bayer CropScience (BCS) has developed cotton [*Gossypium hirsutum*] plants that express an insecticidal protein, Cry1Ab, from a common soil bacterium, *Bacillus thuringiensis* subsp. *berliner* (*B.t. berliner*). The Cry1Ab protein is effective in controlling lepidopteran larvae such as bollworm (CBW, *Helicoverpa zea*) and tobacco budworm (TBW, *Heliothis virenscens*) larvae, which are a common pest of cotton. These pests cause severe economic damage to the cotton crop if not controlled. If controlled by chemical pesticides, there is the need for large input annually to control these pests. These plants also contain herbicide tolerant inert ingredient as a selectable marker, the phosphinothricin acetyltransferase (PAT) protein that confers tolerance to glufosinate-ammonium herbicides. Small scale field trial experiments of cotton expressing Cry1Ab protein have shown the plant's ability to protect itself against these pests. This cotton line has been field tested in small scale filed trial experiments, conducted under notifications granted by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). An Experimental Use Permit 264-EUP-140 has been granted for this product in 2006 and 2008.

Bayer CropScience

Transgenic cotton plants expressing Cry1Ab protein provide an excellent addition to growers' options for insect control that reduces or eliminates the need for other insecticide inputs and fits well within an integrated pest management program. Cry1Ab is a protein familiar to the Agency but is has not been used in commercial cotton as a Plant Incorporated Protectant (PIP).

The *cry1ab* gene was isolated from a *B.t. berliner* strain 1715 and modified for expression in plants. The sequence of the protein is compared with the sequence of Cry1Ab proteins used in commercial bio-pesticides such as Dipel® and in transgenic commercial events such as Bt11, which have been approved world-wide by various agencies. Since the trypsin-resistant core from all Cry1Ab proteins have identical N-termini and a similar sequence, it is concluded that BCS' Cry1Ab protein will be as safe as the Cry1Ab proteins already used commercially.

This application contains three copies of the following required information, as defined in EPA form 8570-1, and five copies of draft labeling.

Volume I

Cover letter (this letter)
Transmittal document
Application for Pesticide Registration (EPA Form 8570-1)
Certification with Respect to Citation of Data (EPA Form 8570-34)
Confidential Statement of Formula (EPA Form 8570-4)
Proposed label
Confidentiality classification
Data matrix
Data matrix blacked out

Volume II

Product Characterization of Cry1Ab cotton event T304-40

Volume III

Product Characterization – Nutritional Characterization.

Volume IV

Protein Expression Analysis

Volume V

Analyses of Raw Agricultural Commodity

Volume VI

Structural and Functional Equivalence of Cry1Ab and PAT/bar Proteins Produced in bacteria and plant

Volume VII

ORF Analysis - Toxicology (human health assessment)

Volume VIII

Cry1Ab protein: In vitro digestibility study in simulated intestinal fluid.

Volume IX

Cry1Ab protein: In vitro digestibility study in human simulated gastric fluid.

Volume X

Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens.- supplemental.

Volume XI
Cry1Ab protein: Acute toxicity by oral gavage in mice.

Volume XII
Cry1Ab Protein: Heat Stability study.

Volume XIII
Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.

Volume XIV
Summary of Non-Target Organism Testing.

Volume XV
Honey Bee

Volume XVI
Ladybug

Volume XVII
Green Lacewing

Volume XVIII
Collembola

Volume XIX
Waiver for Non-target Soil Invertebrate Study: Earthworm.

Volume XX
Water Fleas -Daphnia magna

Volume XXI
Bioassay to Determine the DT50 of the Cry1Ab Protein Produced from *Escherichia coli* after Aerobic Soil Degradation.

Volume XXII
Efficacy Assessment (Field and Laboratory)

Volume XXIII
Waiver from the Requirement to Prepare a Public Interest Document.

Volume XXIV
Waiver from the Requirement to Develop an Insect Resistance Management Plan.

Volume XXV
Detection Methods – rt PCR.

Volume XXVI
Detection Methods – LFS.

Volume XXVII
Detection Methods – ELISA.

Bayer CropScience

BCS respectfully requests that BPPD evaluate this application in time to grant a registration January 1, 2010. We request that this submission is processed concurrently to the Cry2Ae cotton submission as the commercial product is dependent on both registrations.

Please do not hesitate to contact me at (919) 549 2159, or FAX: (919) 549 3929 or Email: ali.scott@bayercropscience.com

Sincerely,

Ali Scott Ph.D.
Manager, Regulatory Affairs Region Americas

Bayer CropScience

TRANSMITTAL DOCUMENT

SUBMITTED BY

Bayer CropScience LP- BioScience
P.O. Box 12014
2 T.W. Alexander Dr.
Research Triangle Park, NC 27709

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Section 3 Registration Request for
Bacillus thuringiensis subsp. *berliner* Cry1Ab Insecticidal Protein
(including proteins Cry1Ab and PAT)

DATE

December 22, 2008

Author:

Alejandra (Ali) Scott, Ph.D
Regulatory Affairs Manager, Region Americas

Total pages 1 of 7

LIST OF SUBMITTED DOCUMENTS

Volume I

Scott, A. 2008. Administrative Documents

- Cover letter
- Transmittal document
- Application for Pesticide Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Confidential Statement of Formula (EPA Form 8570-4)
- Proposed label
- Confidentiality classification
- Data matrix
- Data matrix blacked out

MRID Number _____

Volume II

Ferullo, J-M. 2008.
Product Characterization of Cry1Ab cotton event T304-40
Unpublished. Bayer CropScience.

MRID Number **47634801**

Volume III

Nennstiel, D. 2008.
Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40.
Unpublished. Bayer CropScience.

MRID Number **47634802**

Volume IV

Currier, T. and Massengill, J. 2007.
Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1Ab and PAT/*bar* Proteins, USA, 2007.
Unpublished. Bayer CropScience.

MRID Number **47634803**

Volume V

Martone, A. 2008.
Analyses of Raw Agricultural Commodity (Fuzzy Seed) of Cry1Ab Cotton Event T304-40 for PAT/*bar* and Cry1Ab and its Non-transgenic Counterpart for PAT/*bar* and Cry1Ab Proteins.
Unpublished. Bayer CropScience.

MRID Number **47634804**

Volume VI

Martone, A. 2008.
Structural and Functional Equivalence of Cry1Ab and PAT/*bar* Proteins Produced in *Escherichia coli* to Cry1Ab and PAT/*bar* Proteins from Event T304-40 and TwinLink Cotton, *Gossypium hirsutum*. USA, 2008.
Unpublished. Bayer CropScience.

MRID Number **47634805**

Volume VII

Nennstiel, D. 2008.
ORF Analysis - Toxicology (human health assessment)
Unpublished. Bayer CropScience.

MRID Number **47634806**

Volume VIII

Rouquié, D. 2007.
Cry1Ab protein: *In vitro* digestibility study in simulated intestinal fluid.
Unpublished. Bayer CropScience.

MRID Number **47651101**

Volume IX

Rouquié, D. 2007.
Cry1Ab protein: *In vitro* digestibility study in human simulated gastric fluid.
Unpublished. Bayer CropScience.

MRID Number **47651102**

Volume X

Rouquié, D. 2007.
Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens. Supplement to MRID 46708802 and MRID 46708803
Unpublished. Bayer CropScience.

MRID Number **47634809**

Volume XI

Rouquié, D. 2007.
Cry1Ab protein: Acute toxicity by oral gavage in mice.
Unpublished. Bayer CropScience.

MRID Number **47651103**

Volume XII

Rouquié, D. 2007.
Cry1Ab Protein: Heat Stability study.
Unpublished. Bayer CropScience.

MRID Number **47651104**

Volume XIII

Nennstiel, D. 2008.
Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.
Unpublished. Bayer CropScience.

MRID Number **47634812**

Volume XIV

Chalmers, A. 2008.
Summary of Non-Target Organism Testing and Assessment of Risk of *Gossypium hirsutum* Transformation event T304-40 Expressing Cry1Ab Protein.
Unpublished. Bayer CropScience.

MRID Number **47634813**

Volume XV

Richards, K. 2008.
Evaluation of the Dietary Effect(s) of a Cry1Ab Protein on Honey Bee Larvae (*Apis mellifera* L.).
Unpublished. Bayer CropScience.

MRID Number **47651105**

Volume XVI

Patnaude, M. 2008.
Laboratory Study to Determine the Effects of Cry1Ab Protein on the Predatory Beetle *Coleomegilla maculate*.
Unpublished. Bayer CropScience.

Robinson, T.; Currier, T.; Chalmers, A.
Analysis of Insect Diet tested in Study EB99L008 'Laboratory Study to Determine the Effect of Cry 1Ab protein on the Predatory Beetle, *Coleomegilla maculata'*
Unpublished Bayer CropScience

MRID Number **47634815**

Volume XVII

Patnaude, M. 2008.
Cry1Ab Protein. Toxicity to Green Lacewing (*Chrysoperla rufilabris*).
Unpublished. Bayer CropScience.

MRID Number **47634816**

Volume XVIII

Patnaude, M. 2008.
Chronic Toxicity to Collembola (*Folsomia candida*) using Cry1Ab Proteins.
Unpublished. Bayer CropScience.

MRID Number **47651106**

Volume XIX

Bushey, D. 2008.
Request for Waivers from the Requirement to Conduct A Non-target Soil Invertebrate Study: Earthworm.
Unpublished. Bayer CropScience.

MRID Number **47634818**

Volume XX

Sayers, L. 2008.
Cry1Ab Protein – Ten Day Toxicity Test to Water Fleas (*Daphnia magna*) Under Static-Renewal Conditions.
Unpublished. Bayer CropScience.

MRID Number **47634819**

Volume XXI

Martone, A. 2008.
The Use of an Insect *Heliothis virescens* Bioassay to Determine the DT_{50} of the Cry1Ab Protein Produced from Escherichia coli after Aerobic Soil Degradation, USA, 2007.
Unpublished. Bayer CropScience.

MRID Number **47634820**

Volume XXII

Jesudason, P. 2008
Cry 1Ab: Efficacy Assessment (Field and Laboratory)
Unpublished Bayer CropScience

MRID Number **47634821**

Volume XXIII

Bushey, D. 2008
Request for Waiver from the Requirement to Prepare a Public Interest Document. Unpublished. Bayer CropScience

MRID Number **47634822**

Volume XXIV

Bushey, D. 2008
Request for a Waiver from the Requirement to Develop an Insect Resistance Management Plan.
Unpublished. Bayer CropScience.

MRID Number **47634823**

Volume XXV

Nennstiel, D, 2008.
Detection Methods – rt PCR.
Unpublished. Bayer CropScience.

MRID Number **47634824**

Volume XXVI Nennstiel, D, 2008.
Detection Methods – LFS.
Unpublished. Bayer CropScience.

MRID Number **47634825**

Volume XXVII Nennstiel, D, 2008.
Detection Methods – ELISA.
Unpublished. Bayer CropScience.

MRID Number **47634826**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 13, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-404794
EPA File Symbol or Registration Number: 264-RNOU
Product Name: BCS CRY1AB COTTON EVENT T304-40
EPA Receipt Date: 30-Dec-2008
EPA Company Number: 264
Company Name: BAYER CROPSCIENCE LP

Ali Scott
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B800

NEW AI;EUP;PIP;NON-FOOD/FEED OR CROP DESTRUCT;SAP REQUIRED (SUBMITTED BEFORE NEW AI PACKAGE. $75K CREDIT TOWARD NEW AI REGISTRATION);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

THIS DOCUMENT MUST HAVE A COLOR BACKGROUND, ULTRAVIOLET FIBERS AND A WATERMA... SEE BACK. VERIFY FOR AUTHENTICITY.

BNY MELLON, N.A.
PITTSBURGH PA 15262

Bayer

CHECK NO. 3100028517
30-160
433

PAY:
TWO HUNDRED TWENTY THOUSAND FIVE HUNDRED AND 00/100 DOLLARS

VOID 180 DAYS AFTER DATE OF CHECK

DATE: 01-09-09 $******220,500.00

TO THE ORDER OF
ENVIRONMENTAL PROTECTION AGENCY
USEPA WASHINGTON FINANCE CENTER
PESTICIDE REGISTRATION SERVICE
PO BOX 979074
ST. LOUIS MO 63197-9000

Authorized Signatures

⑈3100028517⑈ ⑆043301601⑆ [redacted]⑈

Bayer

U1P/110 BEGBV

VENDOR NO.	VENDOR NAME	DATE	CHECK NO.	CHECK AMOUNT
6768799	Environmental Protection Agency	01-09-09	3100028517	220,500.00

REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT	NET AMOUNT
676879900004	01-05-09	2401201913	220,500.00	0.00	220,500.00

4

Commercial/financial information may be entitled to confidential treatment

Please read instructions on reverse before completing form. Form Approved. No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
264- RNOU

2. EPA Product Manager
Denise Greenway

3. Proposed Classification
[X] None [ ] Restricted

4. Company/Product (Name)
BCS Cry1Ab cotton event T304-40

PM# 92

5. Name and Address of Applicant (Include ZIP Code)
Bayer CropScience – BioScience
2 T.W. Alexander Dr.
Research Triangle Park, NC 27709
[ ] Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. n/a
Product Name

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Cotton seed

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging
[ ] Yes*
[X] No
* Certification must be submitted

Unit Packaging
[ ] Yes
[X] No
If "Yes" Unit Packaging wgt.
No. per container

Water Soluble Packaging
[ ] Yes
[X] No
If "Yes" Package wgt
No. per container

2. Type of Container
[ ] Metal
[ ] Plastic
[ ] Glass
[ ] Paper
[ ] Other (Specify)

3. Location of Net Contents Information
[X] Label [ ] Container

4. Size(s) Retail Container
n/a

5. Location of Label Directions
[X] On Label
[ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[ ] Lithograph
[ ] Paper glued
[ ] Stenciled
[X] Other

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Ali Scott	Manager, Reg Affairs	919 549 2159

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature
Ali Scott

3. Title
Manager, Reg Affairs

4. Typed Name
Ali Scott

5. Date
December 22, 2008

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Bayer CropScience - BioScience. 2 TW Alexander Dr. RTP, NC 27709 (919) 549 2159	EPA Registration Number/File Symbol 264-
Active Ingredient(s) and/or representative test compound(s) Cry1Ab protein and the genetic material necessary for its production in cotton event T304-40	Date December 22, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) n/a	Product Name BCS Cry1Ab cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Ali Scott	Dec 22, 2008	Ali Scott, Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

*Pages 16-22 - *Claimed confidential by submitter*

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and .025 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: December 22 2008		EPA Reg. No.: 264-	Page 1 of 7
Applicant's/Registrant's Name & Address	Bayer CropScience - BioScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: BCS Cry1Ab cotton.	
Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	

Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version. Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 22 2008		EPA Reg. No.: 264-	Page 2 of 7
Applicant's/Registrant's Name & Address	Bayer CropScience - BioScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: BCS Cry1Ab cotton.	
Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	

Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version. Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 22 2008		EPA Reg. No.: 264-	Page 3 of 7
Applicant's/Registrant's Name & Address	Bayer CropScience - BioScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: BCS Cry1Ab cotton.	
Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
				PL	

Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version. Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: December 22 2008		EPA Reg. No.: 264-	Page 4 of 7
Applicant's/Registrant's Name & Address	Bayer CropScience - BioScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: BCS Cry1Ab cotton.	
Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	

Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version. Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: December 22 2008		EPA Reg. No.: 264-	Page 5 of 7
Applicant's/Registrant's Name & Address	Bayer CropScience - BioScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: BCS Cry1Ab cotton.	
Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				PL	

Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

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Signature: Ali Scott	Name and Title: Ali Scott, Regulatory Affairs Manager	Date: December 22, 2008

December 22, 2008

Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard,
2777 S. Crystal Dr.,
Alexandria, VA 22202

Subject: Registration application for BCS Cry1Ab cotton event T304-40 cotton. Active ingredient *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production. Confidentiality classifications for Registration application.

The present letter identifies the confidentiality classification for all of the documents supporting this application.

Volume number	***Content***	***Confidentiality classification***
I	Scott, A. 2008. Administrative Documents. • Cover Letter • Transmittal Document • Registration Application Form • Confidential Statement of Formula (CSF) • Proposed Label • Confidentiality Classification • Data Matrix • Data Matrix blacked out	 • n/a • n/a • A • C • A • n/a • C • A
II	Ferullo, J-M. 2008. Product Characterization of Cry1Ab cotton event T304-40.	B
III	Nennstiel, D. 2008. Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40.	B
IV	Currier, T. and Massengill, J. 2007. Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1Ab and PAT/*bar* Proteins, USA, 2007.	B
V	Martone, A. 2008. Analyses of Raw Agricultural Commodity (Fuzzy Seed) of Cry1Ab Cotton Event T304-40 for PAT/*bar* and Cry1Ab and its Non-transgenic Counterpart for PAT/*bar* and Cry1Ab Proteins.	B
VI	Martone, A. 2008. Structural and Functional Equivalence of Cry1Ab and PAT/*bar* Proteins Produced in *Escherichia coli* to Cry1Ab and PAT/*bar* Proteins from Event T304-40 and TwinLink Cotton, *Gossypium hirsutum.* USA, 2008.	B

VII	Nennstiel, D. 2008. ORF Analysis - Toxicology (human health assessment).	B
VIII	Rouquié, D. 2007. Cry1Ab protein: *In vitro* digestibility study in simulated intestinal fluid.	B
IX	Rouquié, D. 2007. Cry1Ab protein: *In vitro* digestibility study in human simulated gastric fluid.	B
X	Rouquié, D. 2007. Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens. Supplement to MRID 46708802 and MRID 46708803.	B
XI	Rouquié, D. 2007. Cry1Ab protein: Acute toxicity by oral gavage in mice.	B
XII	Rouquié, D. 2007. Cry1Ab Protein: Heat Stability study. Vol XII	B
XIII	Nennstiel, D. 2008. Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.	B
XVI	Chalmers, A. 2008. Summary of Non-Target Organism Testing and Assessment of Risk of *Gossypium hirsutum* Transformation event T304-40 Expressing Cry1Ab Protein.	B
XV	Richards, K. 2008. Evaluation of the Dietary Effect(s) of a Cry1Ab Protein on Honey Bee Larvae (*Apis mellifera* L.).	B
XVI	Patnaude, M. 2008. Laboratory Study to Determine the Effects of Cry1Ab Protein on the Predatory Beetle *Coleomegilla maculate*.	B
XVI	Robinson, T.; Currier, T.; Chalmers, A. Analysis of Insect Diet tested in Study EB99L008 'Laboratory Study to Determine the Effect of Cry 1Ab protein on the Predatory Beetle, *Coleomegilla maculata'*.	B
XVII	Patnaude, M. 2008. Cry1Ab Protein. Toxicity to Green Lacewing (*Chrysoperla rufilabris*).	B
XVIII	Patnaude, M. 2008. Chronic Toxicity to Collembola (*Folsomia candida*) using Cry1Ab Proteins.	B
XVI	Bushey, D. 2008. Request for Waivers from the Requirement to Conduct A Non-target Soil Invertebrate Study: Earthworm. Vol XIX	B
XX	Sayers, L. 2008. Cry1Ab Protein – Ten Day Toxicity Test to Water Fleas (*Daphnia magna*) Under Static-Renewal Conditions.	B
XXI	Martone, A. 2008. The Use of an Insect *Heliothis virescens* Bioassay to Determine the DT_{50} of the Cry1Ab Protein Produced from Escherichia coli after Aerobic Soil Degradation, USA, 2007.	B
XXII	Jesudason, P. 2008. Cry 1Ab: Efficacy Assessment (Field and Laboratory).	B
XXIII	Bushey, D. 2008. Request for Waiver from the Requirement to Prepare a Public Interest Document.	B
XXIV	Bushey, D. 2008. Request for a Waiver from the Requirement to Develop an Insect Resistance Management Plan.	B
XXV	Nennstiel, D, 2008. Detection Methods – rt PCR. Vol XXV	B
XXVI	Nennstiel, D, 2008. Detection Methods – LFS. Vol XXVI	B
XXVII	Nennstiel, D, 2008. Detection Methods – ELISA. Vol XXVII	B

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